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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,312	04/13/2001	Lisbeth Illum	8567-603US (WESR/P21598US	2569

570 7590 11/04/2005

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,312	ILLUM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,20,31,34-37,40-49,54 and 59-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,20,31,34-37,40-49,54 and 59-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and request for extension of time, all filed 08/17/05. Examiner further acknowledges receipt of copy of provisional application, number 60/043403 filed April 4, 1997. Claims 7, 20, 31, 34-37, 40-49, 54 and 59-66 are pending.

Priority

Applicants claim foreign priority to GB application number 9822170.8 filed 10/13/1998, however, fexofenadine in amount of 0.5% to 40% does not have support in the foreign priority document as in for example claims 35 and 41 and claims directed to the unsupported percent amounts do not therefore have the benefit of the priority document date of 10/13/1998; those claims reciting the percent amounts have the benefit of the effective filing date of the examined application of 10/12/1999 (*In re Gostelli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (foreign priority application's disclosure of chemical subgenus was insufficient written description to support genus claims of corresponding U.S. application)).

Response to Applicants' Remarks on Magee:

Magee and Marfat have common inventor and assignee and as such the connection regarding the date may still have been made considering the closely related subject matter. However, the statement in [0001] of Magee stating that the invention in Magee differs from the invention in the cited related applications and patents appears to be persuasive.

Thus in light of the above, Magee in not art since the effective filling date is Jan. 31, 2001, which is after the effective date of 10/12/1999 or 10/13/1998.

Claim 35 has two periods and a claim ends in a period. A period appears in 35 (iii) after "agent," and a period appears after "eye" in the last line of the claim. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

1. The rejection of claims 7, 20, 34 and 45 under 35 U.S.C. 102(e) as being anticipated by Magee et al. (US 2002/0111495) is withdrawn in light of applicants' persuasive argument.

Claim Rejections - 35 USC § 103

2. The rejection of claims 35-37, 30-33, 41, 46, 52-54 and 58 under 35 U.S.C. 103(a) as being unpatentable over Magee et al. (US 2002/0111495) is withdrawn in light of applicants persuasive argument.

3. The rejection of claims 7, 20, 21, 28, 29, 34 and 35-51 under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 4,254,129) in view of Magee et al. (US 2002/0111495) is withdrawn because Magee is not available as art against the instant claims.

4. The rejection of claims 7, 20, 21 and 29-58 under 35 U.S.C. 103(a) as being unpatentable over Hwang et al. (US 6,451,815) in view of Magee et al. (US 2002/0111495) is withdrawn because Magee is not available as art against the instant claims.

5. Claims 7, 34-37, 40-48 and 59-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (US 5,476,654) in view of Lech (US 6,027,746).

Claim 34 is directed to composition that is consisting essentially of (i) fexofenadine or a pharmaceutically acceptable salt thereof, (ii) a pharmaceutical excipient that increases the

solubility of the fexofenadine or salt in water selected from the group consisting of a cyclodextrin, and glycofurol, and (iii) thickening agent, which composition is adapted for delivery of the fexofenadine or pharmaceutically acceptable salt thereof to the eye. Thickening agent is generic and would read on any known thickening agent in the art.

In claims 34 and 35, "composition ... adapted for delivery of the fexofenadine or pharmaceutically acceptable salt thereof to the eye" is a future intended use of a composition and is not accorded patentable weight because future intended use is not accorded patentable weight. The comprising language of claim 35 is open.

Conte discloses a composition comprising terfenadine and beta-cyclodextrin and polyvinylpyrrolidone and cornstarch and magnesium stearate (Example 14). In Examples 11, Conte discloses composition that contains terfenadine and cross-linked sodium carboxymethylcellulose and terfenadine is at 20%. In Example 13, terfenadine is formulated with beta-cyclodextrin and terfenadine is at 29%. Conte discloses the composition can be prepared with "cross-linked sodium carboxymethylcellulose, cross-linked polyvinylpyrrolidone, carboxymethyl starch, potassium methacrylate-divinylbenzene copolymer (amberlite IRP88), polyvinylalcohols, hydroxypropylcellulose, hydroxypropylcyclodextrin, alpha, beta, gamma cyclodextrin or derivatives and other dextran derivatives, glucans, scleroglucans and derivatives." The celluloses and the polyvinyl alcohols are thickening agents (see instant claims 59-62 and also column 9, lines 19-25 of Calanchi et al. in US 5,008,117 as a teaching reference). Thus, these thickening agents read on the generic recitation of thickening agents in claims 34, 35. The β-cyclodextrin used in the formulation of terfenadine reads on claim 7. The hydroxypropyl β-cyclodextrin reads on the hydroxypropyl β-cyclodextrin of claim 36. Regarding claims 59,

60, 63 and 64, the prior art discloses that polyvinyl alcohol and cyclodextrin derivatives that encompass the limitations in those claims. While Example 14 discloses a terfenadine composition that comprises cornstarch, any of the thickening agents disclosed by Conte can be used in place of the cornstarch with the expectation that any of the disclosed thickening agents would thicken the composition.

Regarding claims 40 and 41, Conte disclose cellulose-thickening agent and also discloses water and thus aqueous vehicle. Regarding the amount of the excipient, a person of ordinary skill in the art would be able to determine the amount of excipient required in the composition and absent factual evidence, the recited amount of the excipient does not patentably distinguish the claimed invention over the prior art. Generally, differences in amounts of the disintegration agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. "W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The amount of the active agent recited in the claims does not patentably distinguish the invention over the prior art absent a factual evidence showing that it does.

However, Conte does not teach fexofenadine, the metabolite of terfenadine (applicants' admitted art at [0003] and pages1189-1190 of the 1998 Physician Desk Reference as teaching references) as the active agent. But Lech discloses that terfenadine and fexofenadine are antihistamines and are equivalent (column 4, lines 7 and 8; and claim 8; applicants' admitted prior art as a teaching reference at [0003]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the terfenadine

composition as disclosed by Conte. One having ordinary skill in the art would have been motivated to prepare the composition of Conte using fexofenadine as the active agent with the expectation of producing a formulation that would produce antihistaminic activity since it is known in the art that they are both antihistamines and are equivalent.

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433, (MPEP 2112.01 [R-2] I).

6. Claims 20, 31, 49 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not disclose administering the composition to the eye.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600